



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-0269]

Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act;  
Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a draft guidance for industry entitled "Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act." This guidance sets forth FDA's policy concerning certain prescription requirements for compounding human drug products for identified individual patients under section 503A of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). It addresses compounding after the receipt of a prescription for an identified individual patient, compounding before the receipt of a prescription for an identified individual patient (anticipatory compounding), and compounding for office use.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work to finalize the guidance, submit either electronic or written comments on this draft guidance by

[INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL

REGISTER]. Submit comments on information collection issues under the Paperwork

Reduction Act of 1995 by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information

submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-D-0269 for "Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR

56469, September 18, 2015, or access the information at:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit comments on information collection issues to the Office of Management and Budget in the following ways:

- Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or email to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the title, "Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act; Collection of Information."

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Sara Rothman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, room 5197, Silver Spring, MD, 301-796-3110.

## SUPPLEMENTARY INFORMATION:

### I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act." Section 503A (21 U.S.C. 353a), added to the FD&C Act by the Food and Drug Administration Modernization Act of 1997, describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician, to be exempt from the following three sections of the FD&C Act:

- Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice requirements);
- section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and
- section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)).

A compounded drug product may be eligible for the exemptions under section 503A of the FD&C Act only if it is, among other things, compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient. Among other conditions, to qualify for the exemptions under section 503A of the FD&C Act, the drug product must be compounded by a licensed pharmacist in a State-licensed pharmacy or a Federal facility, or by a licensed physician (section 503A(a)).

This guidance sets forth FDA's policy concerning certain prescription requirements for compounding human drug products for identified individual patients under section 503A of the

FD&C Act. It addresses compounding after the receipt of a prescription for an identified individual patient, compounding before the receipt of a prescription for an identified individual patient (anticipatory compounding), and compounding for office use.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the prescription requirement under section 503A of the FD&C Act. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information that they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this document, FDA invites comments on the following topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection

of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Under the draft guidance, if it is not obvious from a prescription order that the prescription is for a compounded drug product, a compounder may consult with the prescriber to determine whether the patient needs a compounded drug and make an appropriate notation on the prescription order. To serve as a basis for compounding under section 503A of the FD&C Act, a notation must document the prescriber's determination that a compounded drug is necessary for the identified patient. FDA recommends using the following statement:

Per [type of communication] with [name of prescriber] on [date], [name of prescriber] has advised that compounded [name of drug] is necessary for the treatment of [name of patient].

We estimate that annually a total of approximately 3,444 licensed pharmacists and licensed physicians ("number of respondents" in table 1) will make a notation with this statement on approximately 172,200 prescription orders ("total annual disclosures" in table 1). We estimate that the consultation between the compounder and the prescriber and adding the written statement to each prescription will take approximately 5 minutes per prescription order.

In addition, the licensed pharmacist or licensed physician seeking to compound a drug product under section 503A should maintain records of valid prescription orders received for compounded drug products to demonstrate compliance with the prescription requirement in section 503A(a)(1) of the FD&C Act. For example, this includes records of valid prescription orders and of prescription orders bearing notations that the compounded drug product is

necessary for the identified individual patient as described in section III.A of this guidance and section 503A(a) of the FD&C Act. Because the time, effort, and financial resources necessary to comply with this collection of information would be incurred by licensed pharmacists and licensed physicians in the normal course of their activities, it is excluded from the definition of "burden" under 5 CFR 1320.3(b)(2). FDA understands that maintaining records of prescriptions for compounded drug products is part of the usual course of the practice of compounding and selling drugs and is required by States' pharmacy laws and other State laws governing record keeping by health care professionals and health care facilities.

Under the guidance, licensed pharmacists and licensed physicians should also maintain records of the calculations performed to determine the limited quantities of drug products compounded before the receipt of valid prescription orders under the enforcement policy described in section III.B.2 of this guidance and section 503A(a)(2) of the FD&C Act. These records should clearly reflect the quantity of a particular drug product compounded in advance of receiving prescription orders for identified individual patients that the compounder has kept on hand as stock for distribution, and the basis for the quantity the compounder kept in stock. Under the enforcement policy described in section III.B.2 of this guidance, this would include the quantity of the drug product distributed under prescription orders for identified individual patients during the reference period that the licensed pharmacist or licensed physician selected (i.e., a 30-day period within the last year).

We estimate that annually a total of approximately 10,332 licensed pharmacists and licensed physicians ("number of recordkeepers" in table 2) will maintain approximately 103,320 records ("total annual records" in table 2). We estimate that maintaining the records will take approximately 5 minutes per record.



FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Third-Party Disclosure Burden<sup>1</sup>

Type of Reporting	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Consultation between the licensed pharmacist or licensed physician and the prescriber and adding a notation to document the prescriber's determination that a compounded drug is necessary for an identified patient.	3,444	50	172,200	0.083 (5 minutes)	14,350

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Annual Recordkeeping Burden<sup>1</sup>

Type of Recordkeeping	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Records of calculations performed to determine "limited quantities."	10,332	10	103,320	0.083 (5 minutes)	8,610

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

### III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>

or <http://www.regulations.gov>.

Dated: April 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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